K02 2044

9. 510(K) SUMMARY

AUG 2 3 2002

Submitted By: Mark Bleyer, President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355
June 20, 2002

Names of Device:
Trade Name: SURGISIS® Staple Line Reinforcement
Common/Usual Name: Surgical Mesh, Staple Line Bolster
Proposed classification name: Surgical Mesh
21 CFR 878.3300 (79 FTM)
Class II

Intended Use:
The SURGISIS® Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The device may be used for buttressing and reinforcing staple lines during lung resection (*e.g.*, wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repair, muscle flap reinforcement, rectal and vaginal prolapse repair, reconstruction of the pelvic floor, and repair of hernias (*e.g.*, diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The SURGISIS® Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers. The device is intended for one-time use.

Predicate Devices:
The SURGISIS® Staple Line Reinforcement is similar to predicate devices, including the SURGISIS® Soft Tissue Graft (K980431) and SURGISIS® Peripheral Vascular Patch (K001785) manufactured by Cook Biotech Incorporated, the Peri-Strips® Staple Line Reinforcement- Strip (K983162) manufactured by Biovascular Incorporated, and the Seamguard® Staple Line Reinforcement Material (K010936) manufactured by W.L. Gore & Associates.

Device Description:
The SURGISIS® Staple Line Reinforcement is manufactured from porcine small intestinal submucosa and is supplied in nominal strip sizes (unfolded) of 1 × 10.7 cm, 1.2 × 13.2 cm, and 1.2 × 17.3 cm. The device is packaged in sterile, sealed double pouches.

Substantial Equivalence:
The SURGISIS®Staple Line Reinforcement is similar with respect to intended use, materials and technological characteristics to predicate devices in terms of 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The material comprising the SURGISIS®Staple Line Reinforcement was subjected to a panel of tests to assess biocompatibility, disinfection, and performance characteristics. The material met the test requirements, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

Conclusions Drawn from the Tests:
The SURGISIS®Staple Line Reinforcement is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2002

Mark Bleyer
President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, Indiana 47906-1076

Re: K022044
Trade/Device Name: Surgisis® Staple Line Reinforcement
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: June 20, 2002
Received: June 24, 2002

Dear Mr. Bleyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022044

Device Name: SURGISIS® Staple Line Reinforcement

Indications For Use:

The SURGISIS® Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The device may be used for buttressing and reinforcing staple lines during lung resection (*e.g.*, wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repair, muscle flap reinforcement, rectal and vaginal prolapse repair, reconstruction of the pelvic floor, and repair of hernias (*e.g.*, diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The SURGISIS® Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers. The device is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022044

Prescription Use Y
(Per 21 CFR 801.109)

OR

Over-The-Counter Use